Medtronic

MAR 16 2006

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE K053431

page 1 of 2

Date Prepared:	December 7, 2005
Applicant:	Medtronic Ireland Parkmore Business Park West Galway Ireland
Submission Correspondent:	Michelle Nivala Regulatory Affairs Specialist Medtronic, Inc. 1015 Gramsie Road Shoreview MN 55126-3082 USA
Telephone:	(763) 505 7863
Fax:	(763) 505 7877
E-Mail	michelle.nivala@medtronic.com
Proprietary Name:	Attain Select™ II 6248DEL Delivery Catheter System
Common Name:	Catheter, Percutaneous
Device Classification:	Class II, 21 CFR 870.1250
Product Code:	DQY

Device Description

The Attain Select™ II 6248DEL Delivery Catheter System contains a delivery catheter and an inner catheter. The Delivery Catheter System is used in conjunction with a commercially available Medtronic Attain outer guide catheter. The outer guide catheter is used to gain coronary sinus access. Together, all three catheters function as a telescoping system that can provide additional sub-selecting capabilities. The 6248DEL Delivery Catheter System is available in two models each containing a straight inner catheter and a delivery catheter with either a 90° or 130° curved tip. The inner catheter in both kits is identical

Indications for Use
The Medtronic Attain Select™ II model 6248DEL delivery catheter system is indicated for the delivery of contrast medium and transvenous devices to the coronary sinus and left heart venous anatomy. The delivery catheter system is indicated for use with outer catheters.

Substantially Equivalent Devices:
The Attain Select™ 6238TEL Guide Catheter Set for Left-Heart Delivery uses similar technology and has similar intended uses, function, materials and method of operation to the following predicate devices:

- Medtronic Attain™ Access 6218A Left Heart Delivery System (K#021589, May 30, 2002)
- Medtronic Attain™ Select™ Guide Catheter Set for Left-Heart Delivery (K#042194, cleared September 15, 2004)
- Guidant RAPIDO™ Cut-Away Guiding Catheter (K#031505, cleared June 25, 2003)

Summary of Studies:
Device integrity testing was performed to support the equivalency of the Attain Select™ II 6248DEL Delivery Catheter System to the predicate devices. Testing included mechanical, functional, and biocompatibility testing. The Attain Select™ II 6248DEL Delivery Catheter System met all specified design and performance requirements.

Biocompatibility Information
Medtronic has tested the materials used to fabricate the Attain Select™ II 6248DEL Delivery Catheter System for biocompatibility. The testing performed by Medtronic is consistent with International Standard ISO 10993-1: 2003, "Biological Evaluation of Medical devices- Part 1: Evaluation and Testing." When classified according to this standard, the catheters included in the Attain Select™ II 6248DEL Delivery Catheter System are external communicating devices with limited exposure (<24 hours) to circulating blood.

Sterilization Validation
The Attain Select™ II 6248DEL Delivery Catheter System will be sterilized using a validated Ethylene Oxide (EtO) sterilization process.

Conclusion
Through the data and information presented, Medtronic Ireland considers the Attain Select™ II 6248DEL Delivery Catheter System to be substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2006

Medtronic Ireland
c/o Ms. Clare Higgins
Regulatory Affairs Co-ordinator
Parkmore Business Park West
Galway, IRELAND

Re: K053431
Attain Select II 6248DEL Delivery Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: DQY
Dated: February 13, 2006
Received: February 15, 2006

Dear Ms. Higgins:

This letter corrects our substantially equivalent letter of March 16, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

510(k) Number (if known): K053431

Device Name: Attain Select™ II 6248DEL Delivery Catheter System

Indications For Use: The Medtronic Attain Select™ II model 6248DEL delivery catheter system is indicated for the delivery of contrast medium and transvenous devices to the coronary sinus and left heart venous anatomy.

The delivery catheter system is indicated for use with outer catheters.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053431